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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 09/493,803 01/28/2000 ALLEN G. GOOD AGZ-002 2681 959 01/27/2003 7590 LAHIVE & COCKFIELD **EXAMINER** 28 STATE STREET KRUSE, DAVID H BOSTON, MA 02109 ART UNIT PAPER NUMBER . 1638 DATE MAILED: 01/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  Eachieum of the many be available under the provisions of 37 CFR 1 136(a). In no event, however, may a reply be timely filled the status of the provision of 37 CFR 1 136(a). In no event, however, may a reply be timely filled the period for reply specified above, the maximum of 37 CFR 1 136(a). In no event, however, may a reply be timely filled from the status of the period for reply specified above, the maximum districtly period will gray plant will expire (5) (MONTH's from the maillag date of this communication.  Fabration to reply within the set or extended period for reply will, to satisfy period will gray plant will expire (5) (MONTH's from the maillag date of this communication.  Fabration to reply within the set or extended period for reply will, to satisfy period will gray and will expire (5) (MONTH's from the maillag date of this communication.  Fabration to reply within the set or extended period for reply will, to satisfy the set of the communication, even the provision of the communication.  Fabration to reply within the set or communication of the set of the communication, even the provision of the communication.  This action is FINAL.  2b) Responsive to communication (s) filled on 21 November 2002.  2a) This action is FINAL.  2b) This action is non-final.  3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4) Claim(s) T.8.26.37-39 and 64-69 is/are pending in the application.  4a) Of the above claim(s) is/are allowed.  5) Claim(s) T.8.26.37-39 and 64-69 is/are rejected.  7) Claim(s) is/are allowed.  6) Claim(s) T.8.26.37-39 and 64-69 is/are rejected.  7) Claim(s) is/are subject to restriction and/or election requirement.  Application Papers  Application Papers  10) The drawing(s) filled on is/are: a) accepted or b		Application No.	Applicant(s)	
David H Kruse   1538    - The MAILING DATE of this communication appears on the cover sheet with the correspondenc address - Period for Reply    A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  He period for reply specified above is less than thity (30) days, a very period and the standard of this communication. If the period for reply specified above is here share mailing date of the communication. If the period for reply specified above is here than thity (30) days, a very period part of this communication. If the period for reply specified above is here share mailing case of his communication. If the period for reply specified above is here share than the period for reply specified above is here than the type of the period of the some analysis of the standard period will apply within the standard primitive of this grown of the period of this communication. If the period for reply specified above is here than the type and the standard period will apply within the standard primitive of the period of this communication. If the period of this communication, even if the period day shall be considered thing.  Any reply vectored by the Office laser than three months after the mailing date of his communication, even if thereby fited, may reduce any search of the period of the standard period of the period of the standard period of the period of the standard period of the period of the period of the standard period of the period of	· Office Action Summary	09/493,803	GOOD, ALLEN G.	
Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  Estatesions of time may be available under the provisions of 3 CPR 1.35(a). In ne event, however, may a reply be smely filed after SIX (b) MONTHS from the realize date of this communication.  Estatesions of time may be available under the provisions of 3 CPR 1.35(a). In ne event, however, may a reply be smely filed after SIX (b) MONTHS from the mailing date of this communication.  **Estatesions of time may be available under the provisions of 3 CPR 1.35(a). In ne event, however, may a reply be smely filed after SIX (b) MONTHS from the mailing date of this communication.  **Failure to reply within the set or extended period for reply will, by slabitue, cause the application to become ABANDONED (35 U.S. C) \$1.33.  **Arry reply records by the Office bis than there mornish after the malitime distinct of the secundary semand patent them deplement. Set 37 CPR 1.76(b).  **Status**  **The period communication is produced by the SIX of the secundary semand patent them deplement. Set 37 CPR 1.76(b).  **Status**  1) ② Responsive to communication(s) filed on 21 November 2002.  2a) ☐ This action is FINAL.  2b) ② This action is non-final.  3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4) ② Claim(s)		Examiner	Art Unit	
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THE MAILING DATE OF THIS COMMUNICATION.  Estatesians of time may be available under the provision of 30 CFR 1.13(6). In no event, however, may a neply be timely filed after EX (8) MONTHS from the mailing date of this communication.  If the period for may be possible under the provision of 30 CFR 1.13(6). In no event, however, may a neply be timely filed after EX (8) MONTHS from the mailing date of this communication or the provision of the prov				
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#### **DETAILED ACTION**

# Continued Examination Under 37 CFR § 1.114

1. A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 21 November 2002 has been entered.

## **Drawings**

2. The drawings in this application have been objected to by the Draftsperson as informal. See the PTO-948 form attached to the Office action mailed 12 February 2001. Applicant is reminded that correction of the drawings cannot be held in abeyance, and that formal drawings are required in response to this Office Action as outlined in 37 CFR § 1.85(a). Failure to take corrective action within the set period will be considered non-responsive to this Office action.

#### Claim Rejections - 35 USC § 112

- 3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 4. Claims 7, 8, 26, 37-39 and 64-69 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

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inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a method for directing expression of a target gene within the root of a plant comprising transforming a plant cell with a target gene in operable linkage with an abiotic stress-induced root promoter and a seed comprising said target gene in operable linkage with an abiotic stress-induced root promoter.

Applicant describes the btg26 promoter exemplified by SEQ ID NO: 1 that has root-preferred function and is induced by osmotic-stress and a method of expressing a target gene in a root under osmotic stress conditions (see Example 5 on pages 38-42 of the specification).

Applicant does not describe other abiotic stress-induced root promoters or other btg26 root promoters and thus does not describe a method using other abiotic stress-induced root promoters.

Hence, it is unclear from the instant specification that Applicant was in possession of the invention as broadly claimed.

See, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes,

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even when accompanied by a method of obtaining the claimed sequence. In the instant case, Applicant describes only one species of the genus required to practice the claimed method and make the claimed seed and does not describe what special features are shared by all abiotic stress-induced root promoters as broadly claimed.

5. Claims 7, 8, 26, 37-39 and 64 -68 remain rejected and claim 69 is rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method for directing root-specific expression of a target gene in a plant with the btg-26 promoter of SEQ ID NO: 1 wherein said promoter is osmotically regulated and a seed comprising said promoter, does not reasonably provide enablement for a method for directing root-specific expression of a target gene in a plant with any root-specific promoter and wherein said root-specific promoter is environmentally or developmentally regulated. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for the reason of record as set forth in the last Office action mailed 22 October 2002. Applicant's arguments filed 21 November 2002 have been fully considered but they are not persuasive.

Applicant argues that amendments to the claims to indicate that the promoter is a root promoter more specifically define the subject matter (page 3 of the Remarks/Arguments).

This argument is not found to be persuasive for the reasons given in the previous Office action mailed 22 October 2001. At claim 26, the list of abiotic stress parameters

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exemplifies the Examiner's arguments that undue trial and error experimentation would have been required by one of skill in the art at the time of Applicant's invention to identify and isolate a myriad of abiotic stress-induced root promoters to practice the claimed method and produce the claimed seed within the full breadth of the claims.

# Claim Rejections - 35 USC § 102

6. Claims 7, 8, 26, 37-39 and 64 -68 remain rejected and claim 69 is rejected under 35 U.S.C. §102(e) as being anticipated by Good *et al* (U.S. Patent 6,084,153). This rejection is repeated for the reason of record as set forth in the last Office action mailed 22 October 2001. Applicant's arguments filed 21 November 2002 have been fully considered but they are not persuasive.

Applicant argues that the subject matter of the instant claims pertain to a method of expressing a target gene in a plant using an abiotic, stress-induced root-specific promoter and that there is no teaching within Good *et al* of root-specific expression of a target gene (see page 3 of the Remarks/Argument). This argument is not found to be persuasive because the fact that Good *et al* in the '153 patent does not disclose root-specific promoter activity does not obviate this rejection if the promoter of Good *et al* inherently has such a promoter activity.

See *ex parte* Novitski, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993) (The Board rejected a claim directed to a method for protecting a plant from plant pathogenic nematodes by inoculating the plant with a nematode inhibiting strain of *P. cepacia*. A U.S. patent to Dart disclosed inoculation using *P. cepacia* type Wisconsin 526 bacteria for protecting the plant from fungal disease. Dart was silent as to nematode inhibition

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but the Board concluded that nematode inhibition was an inherent property of the bacteria. The Board noted that applicant had stated in the specification that Wisconsin 526 possesses an 18% nematode inhibition rating).

### **Double Patenting**

7. Claims 7, 8, 26, 37-39 and 64 -68 remain rejected and claim 69 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,084,153. This rejection is repeated for the reason of record as set forth in the last Office action mailed 22 October 2001. Applicant states that a terminal disclaimer will be filed upon an indication from the Examiner that the application is otherwise in condition for allowance (page 4 of the Remarks/Arguments).

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Conclusion

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the

examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703)

306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m.

to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone

number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or

proceeding should be directed to the Group Receptionist whose telephone number is

(703) 308-0196.

AMY J. NELSON, PH.D SUPERVISORY PATENT EXAMINER

Amy Ner

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TECHNOLOGY CENTER 1600

David H. Kruse, Ph.D. 23 January 2003